

REMARKS

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Claims 32-39, 43, 44, 59, 60, 65, 67, 71-74, 82-89 and 93-100 are presently pending in this application. Claims 98 and 99 are deemed allowable. Claims 33, 82 and 88 were amended in the Amendment After Final, mailed February 26, 2002 (a copy of which is attached hereto). Entry of the amendments of claims 33, 82 and 88 is requested.

THE REJECTION OF CLAIMS 32-39, 43, 44, 59, 60, 65, 67, 71-74, 82-89, 93-97 and 100 UNDER 35 U.S.C. §112, FIRST PARAGRAPH

It is asserted in the Advisory Action that Applicant's amendments have not overcome the rejection of claims 32-39, 43, 44, 59, 60, 65, 67, 71-74, 82-89, 93-97 and 100 under §112, first paragraph. Specifically, it is alleged that independent claims 32, 43, 44, 73, 74, 82, 93, 95 and 96, recite the term "cell(s)" and read broadly on all cells, and it is well known in the art that only particular cells, such as a fertilized ovum, would be capable of developing into an animal. It is further asserted that claims dependent on the recited independent claims are included in the rejection as the claims are not complete and are missing critical steps dependent upon the source cells. The rejection is respectfully traversed.

First, as brought to the attention of the Examiner in the Amendment after Final, there are claims pending (i.e., claims 33, 34, 38, 39, 65, 71, 85-89 and 97), in addition to allowed claims 98 and 99, which specify that the cell containing an artificial chromosome is a fertilized ovum, zygote, embryo or mouse embryonic stem cell. Thus, these claims are directed to methods of producing a transgenic non-human mammal or transgenic non-human embryo that include steps of introducing the specified cell into a female, non-human animal or a non-human embryo, and allowing the cell to develop into a non-

human mammal or embryo. It is respectfully submitted that these claims are not within the purview of the rejection because they recite cells or embryos which are compositions that are identified in the Final Office Action and Advisory Action as sufficient for development into an animal, and there is no other basis on which the claims are rejected (since other rejections of claims 33 and 85-89 do not apply to these claims as amended in the Amendment after Final). It is respectfully requested that the Examiner provide clarification as to the specific basis on which claims 33, 34, 38, 39, 65, 71, 85-89 and 97 are rejected.

Second, with respect to the rejection of claims which do not specify a cell type or that recite a cell type other than a fertilized cell or a mouse embryonic stem cell (as well as all of the rejected claims), Applicant has provided evidence [see, *e.g.*, Campbell *et al.* (1996) *Nature* 380:64-66 and PCT Application Publication No. WO95/17500 with publication dates prior to the priority date of the instant application] that fertilization is not essential to the claimed methods. The publications (copies of which are again submitted attached hereto) demonstrate that nuclear transfer methods which can be used for generating transgenic animals, **does not require the use of a fertilized ovum**. The Final Office Action and Advisory Action maintain that any cell that is not a fertilized ovum will not develop into an animal, and that assertion, which underlies almost all of the claim rejections, is simply not correct. It is therefore respectfully submitted that the rejection of claims on this basis cannot validly be maintained.

THE REJECTION OF CLAIMS 32-39, 43, 44, 59, 60, 65, 67, 71-74, 82-89, 93-96, and 100 UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The rejection of claims 32-39, 43, 44, 59, 60, 65, 67, 71-74 and 82-89, 93-96 and 100, directed to a method of producing a transgenic animal or embryo, under 35 U.S.C. §112, second paragraph, is maintained in the Advisory Action. Specifically, it is alleged in the Advisory Action that the claims are incomplete because they are missing critical steps depending upon the source cells. The Final Office Action directs applicant's attention to the "scope of

enablement above." Thus, it appears that the same rejection of the claims is being made under 35 U.S.C. §112, first paragraph, as under 35 U.S.C. §112, second paragraph. The rejection is respectfully traversed.

Claims 98 and 99, which are allowed, are directed to methods for producing a transgenic non-human mammal by introducing a fertilized oocyte containing a satellite artificial chromosome or mouse embryonic stem cell containing a satellite artificial chromosome within an embryo into a female non-human mammal and allowing the embryo to develop into a transgenic mammal. These claims thus specify that the cell containing the satellite artificial chromosome is a fertilized oocyte or mouse embryonic stem cell which are asserted in the Office Action to be sufficient for development into an animal. Because claims 98 and 99 are free of the rejections under 35 U.S.C. §112, they must be considered as complete and not lacking critical steps.

The rejected claims include similar steps and differ from claims 98 and 99 primarily with respect to the cells used in the methods (although, as noted above, many of the rejected claims do not differ from claims 98 and 99 in terms of cells used and thus are not within the purview of this rejection). As described above and discussed in detail in the Response after Final, the claims that do not specify cell type or that specify a cell type other than a fertilized oocyte or mouse embryonic stem cell are complete and enabled since the only basis for the rejection thereof is the allegation that "only a fertilized ovum is capable of developing into an animal" and that allegation is incorrect.

Accordingly, if the rejections under 35 U.S.C. §112 are to be maintained, it is respectfully requested that the "critical steps dependent on source cells" that are alleged to be lacking in all claims except for claims 98 and 99 be specified and clarified.

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HADLACZKY et al.
AMENDMENT

In view of the above amendments and remarks, and the amendments and remarks submitted in the Response after Final, reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,
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